DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Aesculap Implant Systems, Incorporated
Ms. Lisa M. Boyle
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

December 19, 2014

Re: K142707
Trade/Device Name: AIS Odontoid Fracture Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 18, 2014
Received: September 22, 2014

Dear Ms. Lisa M Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I. REQUIRED STATEMENTS

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K142707

Device Name: Aesculap Implant Systems (AIS): Odontoid Fracture Fixation System

Indications for Use:

For fracture fixation of small bones and small bone fragments including odontoid fractures.

Prescription Use ____X____ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Implant Systems (AIS), LLC.
Odontoid Fracture Fixation System

November 12, 2014

COMPANY: Aesculap®Implant Systems (AIS), LLC.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: AIS Odontoid Fracture Fixation System
COMMON NAME: Screw, Fixation, Bone
CLASSIFICATION NAME: Smooth or Threaded Metallic Bone Fixation Fastener
REGULATION NUMBER: 21 CFR 888.3040
PRODUCT CODE: HWC
DEVICE CLASS: Class II

PURPOSE FOR PREMARKET NOTIFICATION

The submission expands the indications for use of the Aesculap Titanium Alloy Bone Screws cleared under K970549.

DEVICE DESCRIPTION

The AIS Odontoid Fracture Fracture Fixation System is comprised of screws and instruments. The 4.0mm cortical screws are either a fully-threaded or partially threaded. They are offered in various lengths and will be non-sterile. The screws are manufactured from titanium alloy (Ti6Al4V) per ISO 5832/3.

INDICATIONS FOR USE

For fracture fixation of small bones and small bone fragments including odontoid fractures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicates)

As is established in this submission, the AIS Odontoid Fracture Fixation System is substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics

to its predicate devices through comparison in design, intended use, material composition, function and range of sizes.

PERFORMANCE DATA

Non-clinical testing was performed to demonstrate that the AIS Odontoid Fracture Fixation System is substantially equivalent to other predicate devices. The following testing was performed:

- Static Testing per ASTMF543
- Static and Dynamic Cantilever Testing per ASTM F2193

The results showed that the subject AIS Odontoid Fracture Fixation System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

PREDICATE DEVICE

- Aesculap Titanium Alloy Bone Screws (K970549)
- BioPro (Millenium Medical) HBS Headless Bone Screw (K020791)
- DePuy Synthes Spine Dens Access System (K132910)